Guidelines for Medical Necessity Determination for Capsule Endoscopy

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for capsule endoscopy. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 433.000 and 450.000, and Subchapter 6 of the *Physician Manual* for information about coverage, limitations, service conditions, and prior-authorization requirements. Providers serving members enrolled in a MassHealth-contracted managed-care organization (MCO) should refer to the MCO's medical policies for covered services.

MassHealth reviews requests for prior authorization on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

Section I. General Information

Capsule endoscopy (CE) consists of the placement of a capsule approved by the FDA for imaging the lumen of the gastrointestinal (GI) tract. It is used primarily as an adjunctive test to determine the etiology and/or location of obscure GI bleeding, and may also be used in the diagnosis of Crohn's disease, or for the identification of previously undocumented lesions in polyposis syndromes. MassHealth considers approval for coverage of CE on an individual, case-by-case basis, in accordance with 130 CMR 433.000 and 450.204, when needed to either diagnose or locate lesions whose identification may result in a change in therapy for the individual.

These guidelines pertain to outpatient use of CE, and therefore are targeted primarily to the evaluation of GI bleeding that is occult, or intermittently overt, rather than active. Therefore, active bleeding is not included in these guidelines.

Section II. Clinical Guidelines

A. Clinical Coverage

MassHealth bases its determination of medical necessity for CE on clinical data, including, but not limited to, indicators that would affect the relative risks and benefits of the procedure. These criteria include, but are not limited to, the following.

1. The images will be interpreted by a clinician with formal training and/or sufficient experience in the interpretation of CE images.
2. The CE procedure must conform to FDA-approved procedures for the particular capsule being used.
3. The member has no evidence from other evaluations of the GI tract that could account for the problems that the CE is intended to identify.

4. The results of the CE must be likely to influence therapeutic decisions about the member's care. For example, if a CE study is performed with the belief that a positive finding will require a surgical intervention, then the member must be a likely surgical candidate at the time of the CE study.
5. **a.** The member must have at least one of the following:
   i. obscure GI bleeding;
   ii. suspected Crohn's disease;
   iii. a polyposis syndrome; or
   iv. an unexplained iron-deficiency anemia.
   b. Other conditions will be considered for approval only in extraordinary circumstances.

B. Noncoverage

MassHealth does not consider CE to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. MassHealth does not pay for experimental or investigational uses.
2. MassHealth does not pay for initial or screening evaluations.
3. MassHealth does not pay for monitoring the course of celiac disease after diagnosis without other indications.
4. MassHealth does not pay for esophageal studies.
5. MassHealth does not pay for any condition in which CE is contraindicated, including
   a. known or suspected GI obstruction, strictures, or fistulas;
   b. individuals with swallowing disorders, unless the capsule can be delivered to the stomach by an alternative method; and
   c. pregnancy.
6. MassHealth does not pay for colonic CE.

Section III. Submitting Clinical Documentation

Requests for prior authorization for CE must be accompanied by clinical documentation that supports the medical necessity for this procedure.

A. Documentation of medical necessity must include all of the following:

1. the primary diagnosis name and ICD-9-CM code pertinent to the clinical symptoms;
2. secondary diagnosis name(s) and ICD-9-CM code(s) pertinent to comorbid condition(s);
3. a summary of the medical and surgical history;
4. if the CE is being performed for the evaluation of obscure GI bleeding, include evidence of substantial GI bleeding and/or lab results supporting the presence of iron-deficiency anemia (Occult-blood positive stool without iron-deficiency anemia is not, by itself, sufficient evidence.);
5. report of colonoscopy, plus results of any biopsies obtained that were performed within two years of the prior-authorization request;
6. documentation for evaluation of the upper GI tract, which varies depending on the following clinical considerations:
   a. for obscure GI bleeding, include the results of <u>two</u> evaluations of the upper GI tract, both of which were performed within two years of the prior-authorization request for CE. One of these must be esophagogastroduodenoscopy (EGD); a second study may be EGD or computed tomography (CT) enterography;
   b. for initial diagnosis of suspected Crohn's disease, only one upper GI tract evaluation is required, but it must include at least one of the following: CT enterography or upper gastrointestinal (UGI) series with small bowel follow-through;

7. for subsequent (including post-op) evaluation of already diagnosed Crohn's disease, indicate current therapy, if any, and what changes in therapy are anticipated if CE is positive for Crohn's lesions;
8. documentation of the most recent physical exam; and
9. other clinical information that MassHealth may request.

B. Clinical information must be submitted by the clinician who will be performing and interpreting the CE study. Providers are strongly encouraged to submit requests electronically. Providers must submit all information pertinent to the diagnosis using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form and attaching pertinent documentation. Questions about POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

Select References

Leighton JA, Goldstein J, Hirota W, et al. Obscure gastrointestinal bleeding. *Gastrointest Endosc.* 2003;58:650-665.

Mishkin D, Chuttani R, Croffie J, et al. ASGE Technology Status Evaluation Report: wireless capsule endoscopy. *Gastrointest Endosc.* 2006;63:539-545.

Sidhu R, Sakellariou P, McAlindon ME, et al. Is formal training necessary for capsule endoscopy? The largest gastroenterology trainee study with controls. *Digestive and Liver Disease.* 2008;40:298-302.

Singh V, Alexander J. The evaluation and management of obscure and occult gastrointestinal bleeding. *Abdom Imaging*. 2009;34:311-319.

Solem C, Loftus E, Joel F, et al. Small-bowel imaging in Crohn's disease: a prospective, blinded, 4-way comparison trial. *Gastrointest Endosc.* 2008;68:255-265.

Van Gossum A, Munoz-Navas M, Fernandez-Urien I, et al. Capsule endoscopy versus colonoscopy for detection of polyps and cancer. *N Engl J Med*. 2009;361:264-270.

These Guidelines are based on review of the medical literature and current practice in capsule endoscopy. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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